

Mass Comm Protocol Changes (Version 1.4 and 1.5)  
04Apr08

<b>PAGE, SECTION, PARAGRAPH</b>	<b>OLD TEXT</b>	<b>NEW TEXT</b>	<b>REASON FOR CHANGE</b>
Cover page, footers, Global change	Version 1.3, 11/02/2007	Version 1.4, 3/25/2008	Updated protocol version number to reflect current version number and date.
Page 12, Section 3.0, Study Design, 6 <sup>th</sup> paragraph	The clinical events committee (CEC) will be blinded to the assigned treatment (PCI setting of SOS vs non-SOS site) arm for the entire study.	The clinical events committee (CEC) will be blinded to the assigned treatment (PCI setting of SOS <b>vs.</b> non-SOS site) arm for the entire study.	Changed vs to vs.
Page 14, Section 3.1.1 Angiographic Inclusion Criteria, #11		<b>We are now allowing PCI within MASS COMM of an infarct (if not treated with primary PCI) or non-infarct-related artery with a 70% or greater stenosis (by visual estimate) &gt; 72 hours following the STEMI. Lesions treated with PCI &gt; 72 hours following STEMI would be subject to the same protocol inclusion/exclusion criteria as noted below (although 70% stenosis would suffice in the absence of recurrent symptoms or abnormal stress test).</b>	Added inclusion criteria to allow enrollment of patients with STEMI.
Page 14, Section 3.1.2 Exclusion	Evidence of ST segment	Evidence of ST segment elevation myocardial	Previously added note deleted to reduce confusion at the sites.

Criteria, #2	<p>elevation myocardial infarction within 72 hours of the intended treatment on infarct related or non-infarct related artery, or other signs and symptoms of an infarction in development as evidenced by clinical symptoms or cardiac enzyme results (except as permitted in inclusion criterion #6 above).</p> <p><u>Note:</u> Subjects undergoing PCI of a non-infarct related artery within 72 hours of STEMI (not treated with reperfusion or primary PCI) are excluded.</p>	<p>infarction within 72 hours of the intended treatment on infarct related or non-infarct related artery, or other signs and symptoms of an infarction in development as evidenced by clinical symptoms or cardiac enzyme results (except as permitted in inclusion criterion #6 above).</p>	
Page 23, Section 4.8.3 Additional Angiography and Revascularization, Table3, Schedule of Events, Row	X (within 12 hours)	X (within <b>24</b> hours)	Changed requirement for collection of pre-procedure enzymes from within 12 hours of procedure to within 24 hours of procedure.

Cardiac Enzymes, CK,CK-MB, Column Pre- Procedure (Within 7 days)			
Page 34, Section 6.0, Definitions	<b>AND</b> at least one of the following criteria, has been fulfilled within a 48 hours time window:	<b>AND</b> at least one of the following criteria has been fulfilled within a 48 hours time window:	Comma was deleted for grammatical accuracy.
Page 18, Section 4.3 Baseline Procedures, Bullet 2	Routine laboratory tests including complete blood count (CBC), platelet count, and serum creatinine obtained within 7 days prior to the index procedure	Routine laboratory tests including complete blood count (CBC), platelet count, and serum creatinine obtained within <b>14</b> days prior to the index procedure	Increased the pre-index procedure window in which baseline labs may be collected from 7 to 14 days.